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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Product and Clinical Development of Tumor Vaccines; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

The Food and Drug Administration (FDA) is announcing the following public workshop: Product and Clinical Development of Tumor Vaccines. This workshop, which is cosponsored by FDA and the National Institutes of Health, will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

Date and Time: The public workshop will be held on Thursday, December 10, 7:30 a.m. to 5 p.m., and Friday, December 11, 1998, 8 a.m. to 5:30 p.m.

Location: The public workshop will be held at the Jack Masur Auditorium, Bldg. 10, National Institutes of Health, 9000 Rockville Pike, Bethesda, MD 20892.

Contact: Abdur Razzaque, Center for Biologics Evaluation and Research (HFM–530), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0675.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number) to Karen Blackburn, Tascon, Inc., 1803 Research Blvd., suite 305, Rockville, MD 20850, 301–315–9000, ext. 514, FAX 301–738–9786, or e-mail kblackburn@tascon.com.

On December 10, 1998, beginning at 7:30 a.m., registration will be held at the public workshop location on a space available basis. However, because space is limited, interested parties are encouraged to register early. There is no registration fee for the public workshop.

If you need special accommodations due to a disability, please contact Karen Blackburn at least 7 days in advance.

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SUPPLEMENTARY INFORMATION: The goals of the workshop include discussing the following: (1) Regulatory considerations in the clinical development process for tumor vaccines; (2) morphological, immunophenotypic,and functional characteristics of dendritic cells; (3) current methods for physicochemical and functional characterization of autologous and allogeneic whole cell tumor vaccines, tumor cell lysates, polyvalent tumor antigen preparations, antigen presenting cells and other cell-derived vaccines; (4) novel preclinical strategies and biological/immunological assessments in early clinical trials; and (5) issues regarding the detection and monitoring of tumor cell contamination in cellular vaccines. The information obtained from these discussions will assist FDA and the interested public in developing policies and standards for product and clinical development for tumor vaccines.

Transcripts: Transcripts of the public workshop may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

Dated: October 21, 1998

William K. Hubbard
Associate Commissioner
for Policy Coordination

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